

WHAT IS CLAIMED IS:

1. (Currently Amended) A method for preparing poorly water soluble drug particles comprising the steps of:

5 dissolving a drug in at least one organic solvent to form a drug/organic mixture; spraying the drug/organic mixture via an atomizing device into an aqueous solution, wherein at least one particle stabilizer is originally present in the aqueous solution, the drug/organic mixture or both the aqueous solution and the drug/organic mixture, and wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution;

and

concurrently evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles, thereby causing the stabilizer to cover the drug particles as the organic solvent is evaporated.

15 2. (Cancelled).

3. (Cancelled).

4. The method according to Claim 2 wherein the particle stabilizer is a surfactant, a polymer, or a dispersion aid.

5. The method according to Claim 4 wherein the particle stabilizer is an absorption enhancer for bioavailability.

6. The method according to Claim 4 wherein the particle stabilizer in the aqueous solution is different than the particle stabilizer in the drug/organic mixture.

7. The method according to Claim 4 wherein the particle stabilizer in the aqueous solution is the same as the particle stabilizer in the drug/organic mixture.

8. The method according to Claim 3 wherein the weight ratio of drug to particle stabilizer is from 0.1:1 to 10:1.

9. The method according to Claim 2 wherein the particle stabilizer is selected from the group consisting of surfactants, phospholipids, copolymers, and homopolymers.

10. The method according to Claim 9, wherein the particle stabilizer is nonionic, anionic, cationic or zwitterionic.

11. The method according to Claim 1 further comprising the step of adding one or more excipients.

12. The method according to Claim 11 wherein the excipients are originally present in the aqueous solution, the drug/organic mixture, or both.

13. The method according to Claim 11 wherein the excipients are added to the aqueous dispersion after the drug particles are formed.

5 14. The method according to Claim 11 wherein the excipients are selected from the group consisting of polymers, absorption enhancers, solubility enhancing agents, dissolution rate enhancing agents, stability enhancing agents, bioadhesive agents, controlled release agents, flow aids and processing aids.

10 15. The method according to Claim 1 wherein the drug/organic mixture is a solution, an emulsion or a microemulsion.

16. The method according to Claim 1 wherein the temperature of the drug/organic mixture is at a level which allows for rapid evaporation of the solvent.

17. The method according to Claim 1 wherein the temperature of the aqueous phase is from about 10°C to 120°C.

15 18. The method according to Claim 1 wherein a portion of the aqueous solution is sprayed together with the drug/organic mixture into the remaining portion of the aqueous solution.

19. The method according to Claim 1 further comprising the step of recovering the particles.

20 20. The method according to Claim 19 wherein recovering the particles comprises removing the water from the particles.

21. The method according to Claim 20 wherein removing the water comprises spray drying, spray freezing, gellation, lyophilization, drying with cold air, or filtration.

25 22. The method according to Claim 1 wherein the average particle diameter of the particles in the aqueous dispersion are from 50 nanometers to about 20 microns.

23. The method according to Claim 1 wherein the spraying occurs through a nozzle.

24. The method according to Claim 23 wherein the nozzle produces a jet comprising fine droplets.

30 25. The method according to Claim 24 wherein the jet results in intense mixing between the drug/organic mixture droplets and the aqueous solution.

26. Drug particles prepared according to the process of Claim 1.

27. (Currently Amended) Poorly water soluble drug particles having an average particle diameter of from 50 nanometers to 20 microns, the drug particles being prepared by a process comprising the steps of:

dissolving the drug in at least one organic solvent to form a drug/organic mixture;

5 spraying the drug/organic mixture into an aqueous solution, wherein at least one particle stabilizer is originally present in the aqueous solution, the drug/organic mixture or both the aqueous solution and the drug/organic mixture, and wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution; and

10 concurrently evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles, thereby causing the stabilizer to cover the drug particles as the organic solvent is evaporated.

28. (Currently Amended) A method for preparing poorly water soluble drug particles comprising the steps of:

dissolving a drug in at least one organic solvent to form a drug/organic mixture;

15 spraying the drug/organic mixture via an atomizing device into an aqueous solution, wherein at least one particle stabilizer is originally present in the aqueous solution, the drug/organic mixture or both the aqueous solution and the drug/organic mixture, and wherein the drug/organic mixture is sprayed at or below the liquid level of the aqueous solution;

20 and

rapidly evaporating the organic solvent in the presence of the aqueous solution to form an aqueous dispersion of the drug particles, thereby causing the stabilizer to cover the drug particles as the organic solvent is evaporated.

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